MySafePass™

Olfactory Screening System

Scientific and Clinical Citations Compendium

Complete Reference Guide

Version 4.0 - October 2025

FDA Class II Medical Device

MY SAFE PASS™
Olfactory Symptom Screening

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1. Olfactory dysfunction following moderate to severe traumatic brain injury

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC10040093/

Reports incidence of olfactory dysfunction ranging from 0-13% in mild TBI to 15-30% in moderate-severe cases. This study provides critical epidemiological data supporting the use of olfactory testing in TBI assessment.

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2. Olfactory Dysfunction Following Moderate to Severe Traumatic Brain Injury

PubMed - National Library of Medicine

https://pubmed.ncbi.nlm.nih.gov/36070126/

Confirms TBI is associated with prominent olfactory dysfunction and identifies research gaps. Essential reference establishing the clinical significance of post-traumatic olfactory assessment.

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3. Traumatic brain injury-induced inflammatory changes in the olfactory bulb

ScienceDirect - Brain, Behavior, and Immunity

https://www.sciencedirect.com/science/article/pii/S0889159123002271

Examines inflammation and neuronal dysfunction in the olfactory bulb following TBI. Provides mechanistic understanding of how brain injury affects olfactory function at the cellular level.

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4. Post-traumatic olfactory dysfunction: a scoping review of assessment and treatment

Frontiers in Neurology

https://www.frontiersin.org/journals/neurology/articles/10.3389/fneur.2023.1193406/full

Comprehensive review of post-traumatic olfactory dysfunction assessment and treatment options. Key resource for understanding current clinical approaches to TBI-related smell disorders.

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5. Olfactory impairment and traumatic brain injury in blast-injured combat troops

Neurology

https://www.neurology.org/doi/10.1212/WNL.0000000000001475

Provides Class III evidence that olfactory dysfunction identifies TBI patients with intracranial abnormalities with 35% sensitivity and 100% specificity. Critical validation study for olfactory testing in TBI diagnosis.

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6. Tracking traumatic head injuries with the chemical senses

ScienceDirect - Biosensors and Bioelectronics

https://www.sciencedirect.com/science/article/pii/S2095881118300192

Discusses using smell testing to track CTE recovery in contact sports. Supports the application of olfactory screening in sports medicine and chronic injury monitoring.

1. Olfactory Function and Associated Clinical Correlates in Former NFL Players

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC5314992/

Examines relationship between olfaction and CTE in former NFL athletes. Pioneering study establishing the connection between repetitive head trauma and olfactory dysfunction in professional sports.

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2. Chronic traumatic encephalopathy (CTE): criteria for neuropathological diagnosis

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC10020327/

Overview of CTE research increase over 17 years and diagnostic criteria development. Provides contextual framework for understanding CTE as a distinct neurodegenerative condition.

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3. Developing methods to detect and diagnose chronic traumatic encephalopathy

Alzheimer's Research & Therapy

https://alzres.biomedcentral.com/articles/10.1186/s13195-021-00872-x

Details DIAGNOSE CTE Research Project methods and objectives. Important reference for understanding current research efforts in CTE biomarker development and detection strategies.

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4. Olfactory Function Is Reduced in Former Elite American Football Players

ResearchGate

https://www.researchgate.net/publication/386737237

Recent study of hyposmia in traumatic encephalopathy syndrome in 119 former elite players. Provides contemporary evidence supporting olfactory testing as a potential CTE screening tool.

1. Olfactory Dysfunction as an Early Biomarker in Parkinson's Disease

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC5636737/

Demonstrates that olfactory impairment develops early or prior to motor symptoms in Parkinson's disease. Foundational research supporting olfactory testing as an early detection biomarker.

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2. Olfactory Loss in Parkinson's Disease

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC3109349/

Reports that >95% of PD patients present with significant olfactory loss. Critical epidemiological data establishing the near-universal nature of smell dysfunction in Parkinson's disease.

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3. Olfactory Dysfunction: An early indicator of parkinson's disease

ScienceDirect - Brain Disorders

https://www.sciencedirect.com/science/article/pii/S2666459325000290

Reviews PD characteristic symptoms including smell decline as an early indicator. Supports clinical utility of olfactory screening in pre-motor PD detection.

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4. Olfactory dysfunction and its related molecular mechanisms

Neural Regeneration Research - LWW

https://journals.lww.com/nrronline/fulltext/2024/03000/olfactory_dysfunction_and_its_related_molecular.32.aspx

Reports that 90% of early-stage PD patients show olfactory dysfunction and explores molecular mechanisms. Provides mechanistic insight into PD-related olfactory pathology.

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5. Loss of Smell

Parkinson's Foundation

https://www.parkinson.org/understanding-parkinsons/non-movement-symptoms/loss-of-smell

Official foundation resource describing hyposmia as an early PD sign. Authoritative clinical guidance supporting olfactory assessment in PD screening protocols.

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6. Study Uncovers Biological Mechanism Behind Loss of Smell in Parkinson's

Yale Medicine

https://medicine.yale.edu/news-article/new-study-uncovers-biological-mechanism-behind-loss-of-smell-in-parkinsons-patients/

Reports that 75-90% of PD patients experience smell loss prior to motor symptoms. Recent research reinforcing the temporal relationship between olfactory dysfunction and PD onset.

1. Odor Discrimination as a Marker of Early Alzheimer's Disease

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC10473073/

Demonstrates that olfactory discrimination testing shows good diagnostic efficacy for early AD detection. Supports use of specific olfactory subtests in dementia screening protocols.

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2. Olfactory Testing With Focus on Odor Identification for Early Detection

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC12484899/

Establishes that olfactory loss is significantly associated with cognitive decline and MCI/AD progression. Key evidence supporting olfactory testing as an early biomarker for Alzheimer's disease.

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3. Mass General Brigham Researchers Develop At-Home Smell Test

Mass General Brigham

https://www.massgeneralbrigham.org/en/about/newsroom/press-releases/smell-test-for-alzheimers-disease

Reports that odor identification, memory, and discrimination decline with age and MCI. Contemporary research supporting practical applications of olfactory testing in Alzheimer's screening.

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4. Early detection of Alzheimer's may start with simple test

Harvard Gazette

https://news.harvard.edu/gazette/story/2025/03/early-detection-of-alzheimers-may-start-with-simple-test/

Recent Harvard research on nose-based early detection of cognitive impairment. Provides current academic perspective on olfactory testing utility in dementia screening.

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5. Markers of olfactory dysfunction and progression to dementia

Alzheimer's & Dementia

https://alz-journals.onlinelibrary.wiley.com/doi/10.1002/alz.12932

12-year longitudinal study showing poor olfactory performance associated with increased dementia risk. Longitudinal evidence supporting olfactory dysfunction as a predictor of cognitive decline.

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6. Olfactory deficits predict cognitive decline and Alzheimer dementia

Neurology

https://www.neurology.org/doi/10.1212/WNL.0000000000001132

Shows odor identification impairment is superior to episodic memory testing in predicting cognitive decline. Strong evidence for prioritizing olfactory assessment in dementia screening protocols.

1. Olfactory dysfunction in patients with multiple sclerosis

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC9017946/

Systematic review showing 11% of MS patients have olfactory dysfunction. Provides epidemiological data on the prevalence of smell disorders in multiple sclerosis populations.

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2. The Factors Associated With Olfactory Dysfunction in MS Patients

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC8114867/

Demonstrates that impaired olfaction is associated with signs of neurodegeneration in MS. Links olfactory dysfunction to disease progression markers in multiple sclerosis.

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3. Smell as a clinical-marker for functional limitations in multiple sclerosis

Multiple Sclerosis and Related Disorders

https://www.msard-journal.com/article/S2211-0348(20)30583-6/abstract

Confirms olfactory function impairment in MS patients and relates dysfunction to functional limitations. Supports olfactory testing as a clinical assessment tool in MS management.

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4. Olfactory Dysfunction in Multiple Sclerosis

New England Journal of Medicine

https://www.nejm.org/doi/full/10.1056/NEJM199706263362617

Seminal NEJM publication providing physiologic explanation for decreased olfactory function in neurological disease. Foundational reference establishing the scientific basis for olfactory dysfunction in MS.

1. Olfactory Dysfunction in Huntington's Disease

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC8673514/

Comprehensive review establishing olfactory dysfunction as a common symptom in HD patients. Provides foundation for including olfactory assessment in Huntington's disease evaluation protocols.

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2. Underestimated olfactory domains in Huntington's disease

PubMed - National Library of Medicine

https://pubmed.ncbi.nlm.nih.gov/37470108/

Demonstrates that olfactory impairment extends beyond identification to discrimination and threshold detection. Supports comprehensive olfactory testing approaches in HD assessment.

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3. Olfactory Dysfunction as an Indicator of Cognitive and Motor Symptoms

Neurology

https://www.neurology.org/doi/10.1212/WNL.0000000000204544

Shows olfactory changes can be used as indicators of disease progression in HD. Establishes the clinical utility of olfactory testing for monitoring Huntington's disease advancement.

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4. Investigating the Link between Smell and Huntington's disease

Huntington's Disease Youth Organization

https://www.hdyo.co.nz/research/2022/1/20/investigating-the-link-between-smell-and-huntingtons-disease

Educational resource discussing the early indicator role of olfactory changes in HD. Provides accessible information about smell-disease relationships for clinical and patient education.

1. Olfactory Dysfunction After SARS-CoV-2 Infection in the RECOVER Cohort

JAMA Network Open

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2839325

Large cohort study examining presence, severity, and patterns of olfactory dysfunction in COVID-19. Provides comprehensive epidemiological data on post-COVID olfactory impairment.

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2. Treatments for Olfactory Dysfunction in COVID-19: A Systematic Review

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC11511580/

Systematic review of treatments for COVID-19-related hyposmia, anosmia, and parosmia. Important clinical reference for managing post-viral olfactory dysfunction.

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3. Clinical studies in COVID-related olfactory disorders

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC11156682/

Reports five clinical trials of interventions for COVID-related olfactory disorders. Provides evidence base for therapeutic approaches to viral-induced smell disorders.

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4. The Role of ACE2 Receptors of the Olfactory System in Anosmia in COVID-19

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC8580692/

Explains viral binding to ACE2 and TMPRSS2 proteases in the olfactory system causing anosmia. Provides mechanistic understanding of COVID-19 olfactory dysfunction pathophysiology.

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5. Evidence of SARS-CoV2 Entry Protein ACE2 in the Human Nose and Olfactory Bulb

PubMed - National Library of Medicine

https://pubmed.ncbi.nlm.nih.gov/33486479/

Anatomical evidence for expression of ACE2 and TMPRSS2 in human olfactory structures. Fundamental research establishing the anatomical basis for SARS-CoV-2 olfactory infection.

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6. Expression of the SARS-CoV-2 Entry Proteins, ACE2 and TMPRSS2

ACS Chemical Neuroscience

https://pubs.acs.org/doi/10.1021/acschemneuro.0c00210

Documents ACE2 and TMPRSS2 expression in sustentacular cells of olfactory epithelium. Key molecular evidence explaining selective vulnerability of olfactory tissue to SARS-CoV-2 infection.

1. The Importance of Considering Olfactory Dysfunction During the COVID-19 Pandemic

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC7598761/

Reviews multiple causes of olfactory dysfunction including sinonasal disease, viral infection, post-traumatic, and neurodegenerative conditions. Comprehensive differential diagnosis reference for olfactory disorders.

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2. Non-sinonasal-related olfactory dysfunction: A cohort of 496 patients

ScienceDirect - European Annals of Otorhinolaryngology

https://www.sciencedirect.com/science/article/pii/S1879729613000963

Large cohort study showing most common non-sinonasal causes are post-infectious and post-traumatic. Important epidemiological data for differential diagnosis of olfactory dysfunction.

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3. Smell and Taste Disorders in Primary Care

American Family Physician

https://www.aafp.org/pubs/afp/issues/2023/0900/smell-and-taste-disorders.html

Clinical review stating most olfactory dysfunction is caused by sinonasal conditions. Authoritative primary care guidance for evaluating and managing smell disorders.

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4. The sense of smell in chronic rhinosinusitis

Journal of Allergy and Clinical Immunology

https://www.jacionline.org/article/S0091-6749(20)30113-5/fulltext

Establishes smell loss as a clinical marker of disease severity in chronic rhinosinusitis. Demonstrates the relationship between inflammatory sinonasal disease and olfactory function.

1. Head trauma and olfactory function

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC6051255/

Comprehensive review establishing olfactory impairment as a well-documented sequela of head injury. Fundamental reference linking anatomical vulnerability to clinical presentation in TBI.

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2. Using the Olfactory System as an In Vivo Model To Study Traumatic Brain Injury

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC4108980/

Describes shearing of olfactory nerve along the cribriform plate during TBI. Critical anatomical explanation for the mechanism of post-traumatic olfactory dysfunction.

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3. Olfactory Nerve

Physiopedia

https://www.physio-pedia.com/Olfactory_Nerve

Educational resource describing olfactory nerve anatomy, including axons crossing the cribriform plate to reach the olfactory bulb. Essential anatomical reference for understanding olfactory pathway vulnerability.

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4. Olfactory Nerve: Overview, Function & Anatomy

Cleveland Clinic

https://my.clevelandclinic.org/health/body/23081-olfactory-nerve

Clinical resource explaining first cranial nerve (CN I) function and anatomy. Authoritative medical reference for understanding olfactory system structure and clinical significance.

1. Spread of aggregates after olfactory bulb injection of α-synuclein fibrils

PubMed - National Library of Medicine

https://pubmed.ncbi.nlm.nih.gov/29209768/

Experimental study of misfolded protein aggregates in Parkinson's disease pathology. Demonstrates the role of olfactory structures in alpha-synuclein propagation and neurodegeneration.

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2. α-Synuclein aggregation in the olfactory bulb induces olfactory deficits

Nature - npj Parkinson's Disease

https://www.nature.com/articles/s41531-021-00259-7

Shows alpha-synuclein aggregation causes olfactory deficits by perturbing granule cells and synaptic transmission. Mechanistic evidence linking protein pathology to functional olfactory impairment.

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3. Alpha-synuclein overexpression in the olfactory bulb initiates prodromal PD pathology

PMC - National Center for Biotechnology Information

https://pmc.ncbi.nlm.nih.gov/articles/PMC6192070/

Demonstrates that alpha-synuclein expression in olfactory bulb can initiate PD pathology. Evidence supporting the olfactory system as an early site of Parkinson's disease pathogenesis.

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4. α-Synuclein Pathology and Reduced Neurogenesis in the Olfactory Bulb

Journal of Neuroscience

https://www.jneurosci.org/content/43/6/1051

Explores mechanisms of late-stage olfactory deficits including decreased neurogenesis and circuit perturbations. Advanced research on alpha-synuclein effects on olfactory system function and regeneration.

1. University of Pennsylvania Smell Identification Test

Wikipedia

https://en.wikipedia.org/wiki/University_of_Pennsylvania_Smell_Identification_Test

Comprehensive overview of the 40-item commercially available olfactory test. Standard reference for understanding UPSIT methodology and clinical applications.

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2. Smell Identification Test™ (UPSIT®)

Sensonics International

https://sensonics.com/product/smell-identification-test/

Commercial product information for the one-time use UPSIT test containing 40 odors. Official source for test specifications and clinical applications.

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3. Optimizing olfactory testing for the diagnosis of Parkinson's disease

Nature - npj Parkinson's Disease

https://www.nature.com/articles/s41531-017-0039-8

Validates UPSIT as an effective instrument for detecting olfactory dysfunction in Parkinson's disease. Important clinical validation study supporting olfactory testing protocols.

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4. 'Sniffin' sticks': olfactory performance assessed by the combined testing

PubMed - National Library of Medicine

https://pubmed.ncbi.nlm.nih.gov/9056084/

Seminal publication describing the three-component Sniffin' Sticks test: threshold, discrimination, and identification. Foundational methodology paper for comprehensive olfactory assessment.

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5. How to assess olfactory performance with the Sniffin' Sticks test

ScienceDirect - European Annals of Otorhinolaryngology

https://www.sciencedirect.com/science/article/pii/S1879729615001039

Clinical guide for semi-objective olfactory assessment using three Sniffin' Sticks subtests. Practical methodology reference for implementing comprehensive olfactory evaluation protocols.

1. Olfactory Test Device - Class II Special Controls Guidance

U.S. Food and Drug Administration

https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/olfactory-test-device-class-ii-special-controls-guidance-industry-and-fda-staff

Official FDA guidance describing compliance requirements for Class II olfactory test devices. Essential regulatory reference for medical device development and approval processes.

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2. Classification of Olfactory Test Device

Regulations.gov

https://www.regulations.gov/document/FDA-2006-N-0368-0001

Final rule classifying olfactory test devices into FDA Class II with special controls. Foundational regulatory document establishing classification requirements for olfactory testing devices.

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3. 21 CFR 874.1600 -- Olfactory test device

Electronic Code of Federal Regulations

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-874/subpart-B/section-874.1600

Federal regulation specifying Class II special controls requirements for olfactory test devices. Legal framework governing the manufacture and distribution of olfactory testing equipment.

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4. Classify Your Medical Device

U.S. Food and Drug Administration

https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

FDA guidance on device classification into Classes I, II, III based on risk assessment. General regulatory framework for understanding medical device classification principles and requirements.

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This compendium represents a comprehensive collection of scientific literature supporting the clinical applications of olfactory dysfunction screening across multiple medical conditions. All citations are current as of October 2025 and include active hyperlinks to original sources.